

REMARKS

Entry of the above amendments to the claims and reconsideration of this application, as amended, is respectfully requested. No new matter is added to this application with this amendment. Claims 13 and 14 were amended by substituting the terms "selective serotonin reuptake inhibitor", "monoamine oxidase inhibitor" and "norepinephrine reuptake inhibitor" for the terms "SSRI", "MAO" and "NERI" respectively. Applicant submits that these abbreviations are well known to one of ordinary skill in the art and have been described in the specification. Support for these amendments is in the specification at page 18, lines 18-34.

Formalities

Applicant notes that in claim 1 of U.S. Patent Application Publication No. US 2002/0086865, which is the published version of this application, the variable "R" on page 19, right column, line 34 after the variable "X<sup>4</sup>" and before the variable "X<sup>5</sup>" should instead be "R<sup>6</sup>". Applicant submits that this variable was recited as "R<sup>6</sup>" in the application as filed. Applicant respectfully requests correction.

The 35 U.S.C. § 112 Rejection of claims 10-11 and 15-16

The Examiner has rejected claims 10-11 and 15-16 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention. Applicant respectfully traverses the 35 U.S.C. § 112, second paragraph rejections of claims 10-11 and 15-16.

The 35 U.S.C. § 112 Rejection of claim 10

Words in a patent "will be given their ordinary and accustomed meaning, unless it appears that the inventor used them differently." *Envirotech Corp. v. Al George Inc.*, 730 F.2d 753, 759, 221 USPQ 473, 477 (Fed. Cir. 1984); *Jonsson v. Stanley Works*, 903 F.2d 812, 14 USPQ 2d 1863, 1871 (Fed. Cir. 1990). The Examiner has stated that the inclusion of the terms "elderly," "acutely ill," "chronically ill," "immunocompromised" and "immunosuppressed" in claim 10 render that claim indefinite. Applicants submit that these terms are not indefinite since these terms clearly describe the condition of the patient being treated. These terms were discussed from page 19, line 30 to page 20, line 18 of the specification in the context of the patient being treated. Applicant submits that the terms "acute," "chronic," "immunocompromised," and "immunosuppression" can be found in Stedman's Concise Medical Dictionary and the terms "elderly" and "ill" can be found in Webster's Dictionary. Applicant submits that these terms, in view of the disclosure provided and in view of their ordinary meaning, are clear to one of ordinary skill in the art and are therefore definite. For this reason applicant respectfully requests the Examiner to reconsider

and withdraw the 35 U.S.C. § 112 rejection of claim 10.

The 35 U.S.C. § 112 Rejection of claims 11 and 15-16

The Examiner then stated that claims 11 and 15-16 are indefinite for containing the trademark/trade name GHRP-1, GHRP-2, IGF-I, IGF-II and SSRI. Applicant agrees with the Examiner's statement that these terms are used to define and describe active agents. However, applicant disagrees with the Examiner's statement that these terms are trademarks or tradenames. The terms are abbreviations, well-known in the art, for the terms growth hormone releasing peptide-1, growth hormone releasing peptide-2, insulin-like growth factor-I, insulin-like growth factor-II and selective serotonin reuptake inhibitor, respectively. The terms GHRP-1, GHRP-2, GHRP-6, IGF-I and IGF-II are discussed in the specification at page 33, lines 1-21. The term SSRI is discussed in the specification at page 18, lines 22-23. Applicant submits that this rejection is therefore improper as these terms are not trademarks or tradenames. For this reason applicant respectfully requests that the Examiner reconsider and withdraw the 35 U.S.C. § 112, second paragraph rejections of claims 11 and 15-16.

The 35 U.S.C. § 102(b) Rejection of claims 1-2, 5-6 and 9-11

Claims 1-2, 5-6 and 9-11 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Carpino et al. (WO 97/24369, hereinafter the '369 reference; and WO 98/58947, hereinafter the '947 reference). Applicant respectfully traverses the 35 U.S.C. § 102(b) rejection of claims 1-2, 5-6 and 9-11.

The Examiner has stated, and applicant agrees, that the instant invention provides a method of *stimulating or increasing appetite* using growth hormone secretagogues of formula I or IA alone or in combination with GHRP-6, GHRP-1, GHRP-2, hexarelin, IGF-I or IGF-II. The '369 and '947 references disclose the use of certain growth hormone secretagogues alone or in combination with GHRP-6, GHRP-1, hexarelin, IGF-I or IGF-II for the treatment of medical disorders associated with deficiency in growth hormone such as, *inter alia*, *obesity* in a human. The Examiner then alleged that the present method of stimulating or increasing appetite using growth hormone secretagogues of formula I or IA alone or in combination with GHRP-6, GHRP-1, GHRP-2, hexarelin, IGF-I or IGF-II is inherently anticipated by the '369 and '947 references as the method steps are the same and the amount of compound used is the same. The Examiner also alleged that claiming a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable.

Applicant submits that the present method of *stimulating or increasing appetite* using growth hormone secretagogues of formula I or IA alone or in combination with GHRP-6, GHRP-1, GHRP-2, hexarelin, IGF-I or IGF-II is not anticipated by the '369 or '947

references. The fact that from a manipulative point of view what is claimed is exactly the same as what was done in the prior art is not determinative of the patentability of a process directed to a new use. Other factors, including the material being treated, must be given weight. *Ex parte Garbo* (POBA 1955) 108 USPQ 379. The discovery of a new use of an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957); and MPEP 2112.02. Also, for a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 43 USPQ 2d 1481, 1490 (Fed. Cir. 1997).

The '369 and '947 references do not disclose or suggest the use of the growth hormone secretagogues in a method of *stimulating or increasing appetite*. The point of novelty of the instant claims is the "method for *stimulating or increasing appetite* in a patient" using the compounds of formula I or IA. Under *Ex parte Garbo* reasoning, the fact that the instant method steps are the same as the method steps in the '369 and '947 references is not determinative of the patentability of the instantly claimed method. In other words, the fact that the same amount of growth hormone secretagogue of formula I or IA is administered in the instant new method of treatment as was administered in the methods of the '369 and '947 references does not render the instant new method of treatment as anticipated. Furthermore, the '369 and '947 references do not disclose a method of *stimulating or increasing appetite* using the growth hormone secretagogues of formula I and IA. Therefore, under *Motorola, Inc. v. Interdigital Tech. Corp.* reasoning, the instantly claimed method of stimulating or increasing appetite is not anticipated by the '369 and '947 references because these references do not disclose or suggest each and every element of the instantly claimed method of treatment. For these reasons applicant respectfully requests that the Examiner reconsider and withdraw the 35 U.S.C. § 102(b) rejection of claims 1-2, 5-6 and 9-11.

The 35 U.S.C. § 103(a) Rejection of claims 12-16

Claims 12-16 have been rejected under 35 U.S.C. § 103(a) as being obvious over the '369 and '947 references in view of Vaccarino et al. (CA 2095788, hereinafter "Vaccarino") and The Merck Manual of Diagnosis and Therapy (16<sup>th</sup> Edition) pages 1529-1534 (hereinafter "Merck"). Applicant respectfully traverses the 35 U.S.C. § 103(a) rejections of claims 12-16.

Claims 12-16 are drawn to a method of stimulating or increasing appetite in a patient by employing compounds of formula I or I-A in combination with an antidepressant such as an SSRI, MAO or atypical antidepressant. The Examiner has acknowledged, and applicant agrees, that the '369 and '947 references do not disclose a method of stimulating or increasing appetite by administering a compound of formula I or I-A and an antidepressant. The Examiner has stated that Vaccarino discloses that a growth hormone secretagogue or a growth hormone releasing factor is known to be useful in a method of treating appetite disorder or stimulating appetite in a patient. The Examiner has also stated that Merck discloses that an antidepressant is known to be useful for stimulating or increasing appetite in a patient. The Examiner has then stated that one of ordinary skill in the art would have been motivated to employ the compounds of formula I and IA in combination with an antidepressant since both growth hormone secretagogues and antidepressants are known to be useful in a method of stimulating or increasing appetite in a patient.

Applicant submits that one of ordinary skill in the art, in view of the combination of the '369, '947, Vaccarino and Merck references, would not have found the present method of treatment of claims 12-16 to be obvious at the time of invention. When analyzing prior art "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). Applicants submit that the combined references do not disclose or suggest a method of *stimulating or increasing appetite* using a combination of a growth hormone secretagogue of formula I or I-A and an antidepressant.

First, the abstract at page 1 of each of the '369 and '947 references disclose a method of treating *obesity* using the compounds of formula I and IA and, in that respect, teach away from a method of *increasing or stimulating appetite* using the compounds of formula I and IA, since the treatment of obesity would require *appetite suppression*, rather than *appetite stimulation*. Second, page 4, line 32 through page 5, line 8 of Vaccarino discloses that GRF, fragments and derivatives thereof are useful for stimulating appetite in a patient and page 7, lines 4-26 of Vaccarino describe that GRF is a 44 amino acid from human pancreatic tumor. The Vaccarino reference does not disclose or suggest that any other growth hormone secretagogue, such as the compounds of formula I and I-A, are useful for increasing or stimulating appetite. Applicant further submits that the compounds of formula I and IA are distinct from and not suggested by the GRF, fragments and derivatives thereof described in Vaccarino. Therefore, one of ordinary skill in the art, prior to the present invention, would not have found it obvious to use the compounds of formula I and IA in a method of increasing or stimulating appetite. Third, Merck indicates that antidepressants can be used to treat depression and thereby alleviate its symptoms of anorexia or decreased

appetite. However, Merck at page 1533, column 2, lines 10-12 also discloses that antidepressants, such as an SSRI, can cause anorexia in some patients in the first few months of treatment. Clearly, for those patients, the antidepressant would not be useful for increasing or stimulating appetite and the Merck reference, in this respect, teaches away from instant claims 12-16.

One of ordinary skill in the art would not be motivated to use a combination of a compound of formula I or I-A with an antidepressant in the present method of treatment since the cited references simply do not suggest such a method. There is no motivation for the instantly claimed method since the '369, '947 and Merck references each, at least in part, teach away from the instant method as claimed. Furthermore, Vaccarino does not suggest or provide motivation to one of ordinary skill in the art for the present method of treatment because the growth hormone secretagogues of formula I and I-A are distinct from, not equivalent to and not suggested by the GRF, fragments and derivatives thereof employed in Vaccarino. Therefore, one of ordinary skill in the art in possession of the '369, '947, Vaccarino and Merck references, prior to the present invention, would not have found it obvious to arrive at the instant method of claims 12-16. For these reasons applicant respectfully requests the Examiner to reconsider and withdraw the 35 U.S.C. § 103(a) rejections of claims 12-16.

The 35 U.S.C. § 103(a) Rejection of claims 17-20

Claims 17-20 have been rejected under 35 U.S.C. § 103(a) as being obvious over the '369 and '947 references in view of Vaccarino, Merck and The Pharmacological Basis of Therapeutics (1996) page 928-932 and 339-430 (hereinafter "PBT"). Applicant respectfully traverses the 35 U.S.C. § 103(a) rejections of claims 17-20.

Claims 17-20 are drawn to a method of stimulating or increasing appetite in a patient by employing compounds of formula I or I-A in combination with an antiemetic or antipsychotic. The Examiner has acknowledged, and applicant agrees, that the '369 and '947 references do not disclose a method of stimulating or increasing appetite by administering a compound of formula I or I-A and an antiemetic or antipsychotic. The Examiner has stated that Vaccarino discloses that a growth hormone secretagogue or a growth hormone releasing factor is known to be useful in a method of treating appetite disorder or stimulating appetite in a patient. The Examiner has also stated that Merck and PBT disclose that an antiemetic or antipsychotic is known to be useful in treating decreasing appetite or anorexia in depression. The Examiner has then stated that one of ordinary skill in the art would have been motivated to employ the compounds of formula I and IA in combination with an antiemetic or antipsychotic since both growth hormone secretagogues and an antiemetic or

antipsychotic are known to be useful in a method of stimulating or increasing appetite in a patient.

Applicant submits that one of ordinary skill in the art, in view of the combination of the '369, '947, Vaccarino, Merck and PBT references, would not have found the present method of treatment of claims 17-20 to be obvious at the time of invention. When analyzing prior art "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). Applicants submit that the combined references do not disclose or suggest a method of stimulating or increasing appetite using a combination of a growth hormone secretagogue of formula I or I-A and an antiemetic or antipsychotic.

First, the abstract at page 1 of each of the '369 and '947 references disclose a method of treating *obesity* using the compounds of formula I and IA and, in that respect, teach away from a method of *increasing or stimulating appetite* using the compounds of formula I and IA, since the treatment of *obesity* would require *appetite suppression*, rather than *appetite stimulation*. Applicant submits that prior to the present invention the compounds of formula I and IA as disclosed in the '369 and '947 references were not known to be useful for increasing or stimulating appetite. Second, page 4, line 32 through page 5, line 8 of Vaccarino discloses that GRF, fragments and derivatives thereof are useful for stimulating appetite in a patient and page 7, lines 4-26 of Vaccarino describe that GRF is a 44 amino acid from human pancreatic tumor. The Vaccarino reference does not disclose or suggest that any other growth hormone secretagogue, such as the compounds of formula I and I-A, are useful for increasing or stimulating appetite. Applicant further submits that the compounds of formula I and IA are distinct from and not suggested by the GRF, fragments and derivatives thereof described in Vaccarino. Therefore, one of ordinary skill in the art, prior to the present invention, would not have found it obvious to use the compounds of formula I and IA in a method of increasing or stimulating appetite.

One of ordinary skill in the art would not be motivated to use a combination of a compound of formula I or I-A with an antiemetic or antipsychotic in the present method of treatment since the cited references simply do not suggest such a method. There is no motivation for the instantly claimed method since the '369 and '947 references at least in part, teach away from the instant method as claimed. Furthermore, Vaccarino does not suggest or provide motivation to one of ordinary skill in the art for the present method of treatment because the growth hormone secretagogues of formula I and I-A are distinct from, not equivalent to and not suggested by the GRF, fragments and derivatives thereof employed in Vaccarino. Therefore, one of ordinary skill in the art in possession of the '369,

'947, Vaccarino, Merck and PBT references, prior to the present invention, would not have found it obvious to arrive at the instant method of claims 17-20. For these reasons applicant respectfully requests the Examiner to reconsider and withdraw the 35 U.S.C. § 103(a) rejections of claims 17-20.

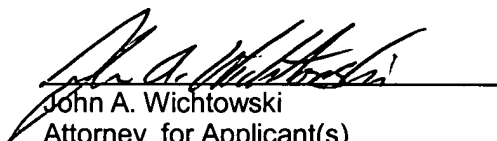
The Examiner has also stated that all active composition components herein are known to be useful to *stimulate or increase appetite* and therefore the claimed invention as a whole is clearly prima facie obvious over the prior art under *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Applicant submits that prior to the present invention the compounds of formula I and IA were not known to be useful in a method of *increasing or stimulating appetite* as discussed above and therefore all active composition components were not known to be useful for *increasing or stimulating appetite*. Therefore, Applicant respectfully submits that under *In re Kerkhoven* reasoning and in light of applicant's comments above, the instant invention is not prima facie obvious.

Applicant, having addressed all points and concerns raised by the Examiner, believes that the application is in condition for allowance and respectfully requests an early and favorable action in light of the foregoing amendment and remarks.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

13. (Once amended) A method of claim 12 wherein said antidepressant is a norepinephrine reuptake inhibitor (~~NERI~~), selective serotonin reuptake inhibitor (~~SSRI~~), monoamine oxidase inhibitor (~~MAO~~), combined norepinephrine reuptake inhibitor NERI/ selective serotonin reuptake inhibitor SSRI, or an atypical antidepressant, a prodrug of said antidepressant or a pharmaceutically acceptable salt of said antidepressant or said prodrug.

14. (Once amended) A method of claim 13 wherein said antidepressant is a selective serotonin reuptake inhibitor (~~SSRI~~), a prodrug thereof or a pharmaceutically acceptable salt of said selective serotonin reuptake inhibitor-SSRI or said prodrug.